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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,488	05/25/2001	Anthony E. Bolton	355908-1650	4401

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,488

Applicant(s)

BOLTON ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-30 and 46-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,23,25-30,46,50 and 52-59 is/are rejected.
- 7) ☒ Claim(s) 20-22,24,47-49 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 2/28/2006 is acknowledged. Claims 19-30 and 46-59 are pending and under consideration. This Office action contains new grounds of rejection. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting, Withdrawn

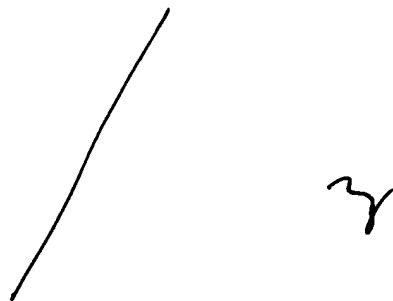
The rejection of the claims under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-28 of Application 09/866,569 is withdrawn in view of the terminal disclaimer.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claim 59 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

The rejection of claims 58, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is also withdrawn in view of the amendment.

The rejection of claims 46-57 under 35 U.S.C. 112, first paragraph, scope of the enablement, is also withdrawn in view of the amendment.

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The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-23, 25-30, 46-50, and 52-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Rook et al., J Investig Dermatol Symp Proc., 1999 Sep;4(1):85-9, as evidenced by Maeda et al., IDS filed on 02/28/2006.

Claims 19, 23, 25-30, 46, 50, and 52-59 are drawn to method of administering apoptotic bodies for treatment and/or prophylaxis of inflammation in a mammalian patients, wherein the apoptotic cells exhibits various art-known characteristics, and the apoptotic cells inhibits and induces certain physiological functions once administered.

Rook et al., teach at the first line of the abstract teach "Photopheresis is a leukapheresis-based therapy that utilizes 8-methoxypsoralen and ultraviolet A irradiation. Photopheresis is currently available at approximately 150 medical centers worldwide." The cells used in "photopheresis" of Rook et al., and the limitation "apoptotic bodies" in the instant base claims 19, 46, 58, and 59 do not appear to have any material differences. Rather the difference is semantic as evidenced by Maeda et al., who teach that "Photopheresis" generates apoptotic cells (note the title, and page 5970, left column under the heading "8-MOP/UVA induce apoptosis").

As for treatment of inflammation, Rook et al., teach “In addition to the treatment of CTCL, numerous reports indicate that photopheresis is a potent agent in the therapy of acute allograft rejection among cardiac, lung, and renal transplant recipients. Chronic graft versus host disease also appears to be quite responsive to photopheresis therapy. Likewise, there may also be a potential role for photopheresis in the therapy of certain autoimmune diseases that are poorly responsive to conventional therapy.”; this indicates that apoptotic bodies had been used for treating inflammation in autoimmune diseases, graft-vs-host diseases, especially given the teachings of the evidentiary reference, Maeda et al., at page 5968, 1st paragraph teach “ECP [extracorporeal photopheresis] has been tried in a variety of diseases that have a suspected involvement of pathogenic T cells, including rejection of organ transplant, graft-vs-host disease and autoimmune disorder (6)”. The reference “(6)” in Maeda et al., is Rook et al.

As for the limitation, reducing Th-1 derived cytokines and up-regulating Th-2 derived cytokines, these are physiological response of administering apoptotic bodies. In other words, it is a natural phenomenon in response to administration of apoptotic cells.

As for the characteristics of apoptotic cells (i.e. DNA fragmentation, surface exposure of phosphatidylserine, etc.), the instant specification at page 2 lines 16 to page 4 discloses that each of the characteristics of apoptotic cells in the instant claims is an alternative way of detecting whether cells undergo apoptosis or not. Therefore, it is concluded that if cells with DNA fragmentation must have surface exposed

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phosphatidylserine or vice versa. In addition, the specification discloses at page 4 pages 13-17 "Methods of quantifying apoptotic cells and apoptotic bodies in a cellular composition are known and readily practiced by persons of skill in the art. Techniques include staining of the treated cell population, with an appropriate, selective dye such as fluorescein-conjugated annexin V, followed by incubation and analysis by flow cytometry." The evidentiary reference (i.e. Maeda et al.) teaches that the cells treated with the same protocol as Rook et al., (i.e. method of xypsores followed by UVA irradiation) are apoptotic bodies as detected by fluorescein-conjugated annexin V, followed by incubation and analysis by flow cytometry (Note Figure 2 of Rook et al., page 5970).

As for the various doses in claims 28-30 and 55-57 in which optimum parameters (from 10,000-10,000,000 to 1,500,000 to 4,000,000, per body weight, i.e. 10,000 % to 270 % difference) are concerned, it is well within the level of ordinary skill in the art to adjust optimum concentrations of each component for specific intended uses, given the review of the treatment protocol of Rook et al. See In re Kronig, 190 USPQ 425.

Conclusion

Claims 20-22, 24, 47-49, and 51 are objected because they depend on the rejected base claims.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2/28/2006 prompted the new ground(s) of rejection presented in this Office action. Applicant's amendment also necessitated the new ground(s) of rejection presented in this Office action.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

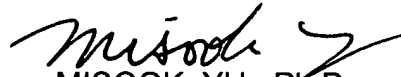
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MISOOK YU, Ph.D.
Primary Examiner
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